UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	
Schering-Plough Corporation, a corporation,	
Upsher-Smith Laboratories, Inc., a corporation,	**Docket No. 9297**
and	
American Home Products Corporation, a corporation.	

UPSHER-SMITH'S STATEMENT OF THE CASE

In compliance with the Scheduling Order dated May 3, 2001, Upsher-Smith hereby provides a statement of the case (i) identifying the factual and legal issues for resolution, (ii) reporting on discovery and (iii) addressing settlement negotiations.

I. FACTUAL AND LEGAL ISSUES

If this proceeding progresses to trial, Upsher-Smith will prove that it did not receive any money or other consideration to delay the introduction of its generic version of K-Dur 20. Upsher-Smith will prove that it resolved Schering's patent-infringement suit in a bona fide settlement allowing it to market its generic on September 1, 2001 — five years before the expiration of Schering's patent — and even earlier if another generic were introduced before then. Upsher-Smith will prove that this settlement was pro-competitive, guaranteeing generic competition five years before it would have occurred if Schering had won the litigation and probably even before it would have occurred if Upsher had won, given the appeal process and the logistics of a new product launch.

At trial Upsher-Smith will disprove the Complaint's allegation that the Schering/Upsher-Smith licensing agreement was a sham intended to disguise a payment to delay generic competition. Upsher-Smith will prove that the licensing agreement was a separate, bona fide transaction, and that the drugs being licensed — most notably Niacor SR but the others as well — had value in line with the consideration received from Schering. In particular, Upsher-Smith will prove that prior to the Schering transaction it had spent in excess of ten million dollars on R&D for Niacor SR over several years and was committed to recouping that expense by licensing the product outside the Untied States. Months before discussing any licensing transaction with Schering, Upsher-Smith had retained a U.K. consultant to identify a European licensing partner for Niacor SR, specifically contemplating substantial upfront payments. Upsher-Smith also had already had substantive discussions with major pharmaceutical companies about licensing Niacor SR in Europe, at least one of which indicated a willingness to pay substantial upfront payments. At the same time, another pharmaceutical company, KOS, had achieved a market value in the hundreds of millions on the strength of an extended-release niacin product similar to Niacor SR.

Complaint Counsel appear intent on denigrating the value of Niacor SR and the other drugs licensed to Schering, exaggerating side effects and regulatory hurdles. This strategy will fail. At trial Upsher-Smith will prove — through fact and expert testimony — that the drugs licensed to Schering had substantial value, commensurate with the consideration paid by Schering, and that the terms of the licensing agreement were otherwise reasonable. Indeed, the evidence adduced will be sufficiently powerful that Complaint Counsel will be forced to retreat from their contention — expressed in open court at the July 25, 2001 hearing (Tr. 37-38) — that the drugs were worthless and that the entire licensing fee paid by Schering to Upsher-Smith was for delay.

Complaint Counsel also appear intent on using 20:20 hindsight to second-guess the consideration paid by Schering. This strategy, too, will fail. A licensing transaction — like any investment — can be fairly assessed only on the basis of the facts and circumstances prevailing at the time that it was entered; many investments may look unwise years later with the benefit of new information and marketplace developments. Upsher-Smith will prove that the drugs it licensed to Schering in 1997 had a value reasonably in the range of what Schering agreed to pay at that time.

At the July 25, 2001 hearing, Complaint Counsel conceded that to win this case they must prove that Schering paid Upsher-Smith to delay entry. Tr. 32, 34-35. Complaint Counsel will not be able to make this showing. Schering paid Upsher-Smith only for the right to market Niacor SR and certain other drugs under the terms of their licensing agreement.

While Upsher-Smith's factual showing ought to dispose of the claims against it, the allegations made by Complaint Counsel raise a host of other issues, including the following: Is the settlement agreement per se unlawful or subject to the rule of reason? Does the settlement agreement fall outside the rule of reason? Is it unlawful even if the payment achieves a procompetitive settlement that is not otherwise achievable? Is it unlawful even if the patent holder would prevail in its claim? Is the amount of the payment relevant? Is nominal consideration permissible? Are generic firms limited by the U.S. antitrust laws to one-dimensional settlements that only involve reducing the time of a patent? Are multifaceted settlement transactions inherently suspect and subject to challenge? Have they been subjected to prior judicial condemnation under the antitrust laws? In an admittedly difficult and expensive patent infringement action, should a patent settlement agreement that shaves off more than half of the remaining life of a patent receive any further second-guessing? Is it the proper function of the law

to second-guess in hindsight the valuation placed on rights or assets by businesspeople? Should hindsight enter into an assessment of the bargained for consideration exchanged in a licensing agreement? Does the law favor the settlement of lawsuits, especially patent-infringement lawsuits?

Did Upsher-Smith have 180-day exclusivity rights upon the settlement with Schering? If not, did it later obtain exclusivity rights? Was any other generic in fact prevented from entering by Upsher-Smith's exclusivity? Could any other generic have triggered Upsher-Smith's exclusivity rights? When would Upsher-Smith have introduced its generic to K-Dur 20 but for the settlement agreement? Is this action, the appropriate forum for redrawing the balance struck by Congress and the Courts in the Hatch-Waxman Act between generic and branded drug firms? What other reasonable substitutes are available for K-Dur 20? Other issues can be expected to arise as this proceeding progresses.

II. DISCOVERY

Upsher-Smith has fully complied with all of Complaint Counsel's discovery demands. Upsher-Smith conducted a painstakingly extensive and costly search of its employees' documents and electronic files, and produced approximately 125 boxes of documents containing well over 200,000 pages. Upsher has also produced its officers, employees and consultants promptly and cooperatively for depositions. Six depositions have occurred, and seven more are scheduled. Apart from depositions, two consultants have responded to subpoenas duces tecum. In addition, Upsher-Smith has timely responded to two sets of requests for admissions. Notably, all of this discovery is in addition to the extensive pre-complaint discovery provided to the Commission and staff.

Illustrative of Upsher-Smith's cooperation is its handling of discovery regarding David Pettit. Your Honor will recall that Complaint Counsel applied unsuccessfully for a subpoena duces tecum addressed to Mr. Pettit, a U.K. citizen and resident. Thereafter, Upsher-Smith arranged for Mr. Pettit to provide all of his documents voluntarily to Complaint Counsel, obviating a renewed application for a subpoena.

Upsher-Smith has served discovery requests of its own, but has not yet received any documents in response. In response to a sweeping request for documents, Complaint Counsel provided boilerplate objections, but no documents. In response to a subpoena duces tecum, the FDA successfully moved to quash. Upsher-Smith is evaluating its options as to these discovery matters, but at a minimum expects to serve subpoenas upon various non-parties in the coming days. Upsher-Smith seeks in particular discovery related to other pharmaceutical companies' marketing of potassium chloride supplements including generic alternatives to K-Dur 20. Expert discovery will commence shortly.

III. SETTLEMENT

Upsher-Smith is not currently engaged in any settlement discussions with Complaint Counsel.

Dated: September 18, 2001

Respectfully submitted,

WHITE & CASE LLP

By: _____

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of September 2001 I caused copies of the foregoing Upsher-Smith's Statement of the Case to be served upon the following by hand delivery:

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
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Sanjiv S. Kala

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